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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte SHINICHIRO MORITA,
TOSHIHARU SHIN `OKA, and YASUHARU IMAI

Appeal[1] 2008-005884
Application 10/070,938
Technology Center 1600

Decided:[2] June 4, 2009

Before DEMETRA J. MILLS, LORA M. GREEN, and JEFFREY N. FREDMAN, *Administrative Patent Judges*.

GREEN, *Administrative Patent Judge*.

DECISION ON APPEAL

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[1] Oral Hearing held May 21, 2009.

[2] The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, begins to run from the decided date shown on this page of the decision. The time period does not run from the Mail Date (paper delivery) or Notification Date (electronic delivery).

This is a decision on appeal under 35 U.S.C. § 134 from the Examiner's final rejection of claims 7-11 and 15-19. We have jurisdiction under 35 U.S.C. § 6(b).

STATEMENT OF THE CASE

The claims are directed to a method of regenerating cardiovascular tissue using a sponge matrix. Claim 7 is representative of the claims on appeal, and reads as follows:

7. A method for regenerating cardiovascular tissue comprising:
seeding cells on a matrix comprising a sponge configured to regenerate cardiovascular tissue and made of a bioabsorbable material and a reinforcement made of bioabsorbable material, the reinforcement being integrated with the sponge and located inside or on the exterior surface of the matrix;
culturing the cells until the matrix is completely covered with the cells; and
embedding the matrix in vivo for regenerating cardiovascular tissue.

The Examiner relies on the following evidence:

Vacanti	US 5,855,610	Jan. 5, 1999
Naughton	US 5,863,531	Jan. 26, 1999
Vyakarnam	US 6,534,084 B1	Mar. 18, 2003
Morita (translation)	JP 3-23864	Jan. 1991

The following grounds of rejection as before us for review:[3]

Claims 7-9, 11, and 15-19 stand rejected under 35 U.S.C. § 103(a) as being obvious over the combination of Vacanti, Vyakarnam, and Morita;

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[3] The Examiner withdrew the rejections of claim 10 under 35 U.S.C. § 103(a) (Ans. 4).

Claims 7, 8, and 11 stand rejected under 35 U.S.C. § 103(a) as being rendered obvious by Naughton;

Claims 9, 15, and 19 stand rejected under 35 U.S.C. § 103(a) as being obvious over the combination of Naughton and Vacanti; and

Claims 16-18 stand rejected under 35 U.S.C. § 103(a) as being obvious over the combination of Naughton, Vacanti, Vyakarnam, and Morita.

We affirm.

PRINCIPLES OF LAW

The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) secondary considerations of nonobviousness, if any. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966).

In *KSR Int'l v. Teleflex Inc.*, 550 U.S. 398, 415 (2007), the Supreme Court rejected a rigid application of a teaching-suggestion-motivation test in the obviousness determination. The Court emphasized that "the [obviousness] analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ."*Id.* at 418. Thus, an "[e]xpress suggestion to substitute one equivalent for another need not be present to render such substitution obvious." *In re Fout*, 675 F.2d 297, 301 (CCPA 1982).

Further,

> [i]f a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill.

Id. at 418.

Under the correct obviousness analysis, "any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed." *Id.* at 420. Thus, for a prima facie case of obviousness to be established, the references need not recognize the problem solved by Appellants. *In re Kemps*, 97 F.3d 1427, 1430 (Fed. Cir. 1996); *In re Beattie*, 974 F.2d 1309, 1312 (Fed. Cir. 1992); *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Int. 1985) ("The fact that appellant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious.")

The burden of demonstrating unexpected results rests on the party asserting them, and "it is not enough to show that results are obtained which differ from those obtained in the prior art; that difference must be shown to be an *unexpected* difference." *In re Klosak*, 455 F.2d 1077, 1080 (CCPA 1972). "[U]nexpected results must be established by factual evidence. Mere argument or conclusory statements in the specification does not suffice." *In re DeBlauwe*, 736 F.2d 699, 705 (Fed. Cir. 1984). "[W]hen unexpected results are used as evidence of nonobviousness, the results must be shown to

be unexpected compared with the closest prior art." *In re Baxter-Travenol Labs.*, 952 F.2d 388, 392 (Fed. Cir. 1991).

ISSUE (Vacanti, Morita, and Vyakarnam)

The Examiner concludes that claims 7-9, 11, and 15-19 are rendered obvious by the combination of Vacanti, Vyakarnam, and Morita.

Appellants contend that the Examiner has failed to establish a prima facie case of obviousness as there is no reason to combine the references as suggested by the Examiner; that Appellants have discovered and solved a problem unknown in the art; and that unexpected results supports the patentability of the claims.

Thus, the issue on appeal is: Have Appellants demonstrated that the Examiner erred in combining the references to arrive at the method of claim 7, does the fact that Appellants discovered and solved a problem unknown in the art demonstrate the nonobviousness of the claims; and if a prima facie case of obviousness has been established, have Appellants demonstrated unexpected results?

FINDINGS OF FACT

FF1 According the Specification, the invention relates to "a method for regenerating cardiovascular tissue such as artificial blood vessel, cardiac valve, pericardium, etc." (Spec. 1.)

FF2 The Specification notes that a sponge meets the basic requirements of a matrix for culturing cardiovascular cells to regenerate cardiovascular tissue as it allows cells to be seeded thereon and adhere thereto, and it enables the matrix to be absorbed in vivo when a blood vessel is regenerated (*id.* at 3).

FF3 The Specification notes further that the "[i]n the case of using the matrix for regenerating a blood vessel, the matrix is required to maintain an [sic] enough strength to endure a blood flow for a certain period of time after implantation till the blood vessel is regenerated in vivo." (*Id.*)

FF4 The Specification teaches that the above requirement may be met by reinforcing the sponge with a bioabsorbable material (*id.*).

FF5 The Specification provides examples of the bioabsorbable material that may be used as the scaffold, which includes "polyglycolic acid, polylactic acid (D form, L form, DL form), polycaprolactone, glycolic acid-lactic acid (D form, L form, DL form) copolymer, glycolic acid-caprolactone copolymer, lactic acid (D form, L form, DL form)-caprolactone copolymer, poly(p-dioxanone) and the like." (*Id.* at 6.)

FF6 The Specification notes, however, that "[t]here is no limitation on the bio-absorbable materials to be used for the sponge and the reinforcement." (*Id.*)

FF7 The Specification provides an Example in vascular regeneration matrix was constructed.

> A glass test tube (10 mm in outside diameter) was wrapped around with a plain-weave cloth of poly-L-lactide fiber (photograph) in a double-cylindrical form. This assembly was set in a mold (12 mm in inside diameter) and a solution of L-lactide-caprolactone copolymer (50:50) in dioxane (5 %) was poured into the clearance, frozen and then lyophilized.

(*Id.* at 12.)

A matrix not reinforced with poly-L-lactide fiber was also produced (*id.* at 13).

FF8 The seeded scaffolds were placed in the inferior vena cava of a young dog (*id.*). According to the Specification, the thoracotomy of dog receiving

the reinforced matrix at the sixth month revealed regeneration of the autogenous blood vessel, whereas the unreinforced matrix "ruptured in one week after substitution and the experimental animal succumbed to sudden death." (*Id.*)

FF9 The Examiner rejects claims 7-9, 11, and 15-19 under 35 U.S.C. § 103(a) as being obvious over the combination of Vacanti, Vyakarnam, and Morita (Ans. 5). As Appellants do not argue the claims separately, we focus our analysis on claim 7, and claims 8, 9, 11, and 15-19 stand or fall with that claim. 37 C.F.R. § 41.37(c)(1)(vii).

FF10 The Examiner finds that Vacanti discloses "reconstruction and augmentation of flexible, strong connective tissue such as arteries and heart valves." (*Id.* (citing Vacanti, col. 1, ll. 4-7).)

FF11 Specifically, the Examiner finds that Vacanti teaches:

> [P]roducing blood vessels, arteries and heart valves (cardiovascular tissue) using steps as claimed by seeding cells on a matrix made of bioabsorbable material configured to regenerate the tissue, culturing the cells on the matrix (Examples 1 and 2), and embedding the matrix *in vivo*, i.e. implanting the matrix containing tissue formed (col 2, lines 41-42, and col 8, line 21).

(Ans. 8.)

FF12 The Examiner finds that Vacanti teaches that the "[s]tructures are created by seeding a fibrous or porous matrix with cells . . . to form tissues having structural elements such as heart valves and blood vessels." (*Id.* at 5-6 (citing Vacanti, col. 2, ll. 65-67; col. 3, ll. 2-3).)

FF13 The Examiner finds also that Vacanti teaches that the "matrix can be sponge like." (Ans. 7 (citing Vacanti, col. 3, l. 51).)

FF14 The Examiner further cites Vacanti for teaching that the "shape of the matrix can be obtained using struts that impart resistance to mechanical forces to yield the desired shape such as heart valve leaflets and tubes." (Ans. 7 (citing Vacanti, col. 3, ll. 62-67 and col. 5, ll. 35-48).)

FF15 Vacanti teaches a structure that is created by seeding of fibrous or porous polymeric matrices with dissociated cells that may be used, among other things, as tissues that have structural elements, such as heart valves and blood vessels (Vacanti, col. 2, l. 65-col. 3, l. 3).

FF16 Vacanti teaches that the matrix is formed of fibers having a fibrous structure, and includes sponge like devices (*Id.* at col. 3, ll. 42-50). Synthetic fibers that are bioerodable include poly(lactide), and natural fibers that are biodegradable include collagen (*id.* at col. 4, ll. 3-39). Vacanti notes that the "erosion of the matrix is related to the molecular weights of the polymer." (*Id.* at col. 4, ll. 65-67.)

FF17 Vacanti teaches that struts, which may be made from a biodegradable polymer that has sufficient strength to resist the necessary mechanical forces, may be used to create a more defined shape for the matrix (*id.* at col. 5, ll. 36-48). The struts may be implanted prior to or at the same time as the matrix (*id.*).

FF18 Vacanti specifically teaches tissue engineering of a heart valve (col. 7, Example 1) and of vascular structure (col. 8, Example 2).

FF19 Morita is cited by the Examiner for teaching a filler material comprising a composite material consisting of collagen and poly-L-lactic acid, for use in the treatment of wounds or defects and in orthopedic surgery (Ans. 8-9).

FF20 The Examiner finds that the filler material has little reactivity with tissue, promotes the proliferation of fibroblasts, and maintains its shape and strength over a long period of time until the tissue is regenerated (*id.* at 9).

FF21 The Examiner finds further that Morita teaches that the use of a biodegradable poly-L-lactic acid with the collagen sponge "makes it possible to maintain structural pores of the sponge over a long period of time, and to promote the propagation of fibroblasts in the interior of the composite material, and maintain the strength and shape over a long period of time required for treatment." (*Id.* at 9-10 (citing Morita, paragraph bridging pp. 2 and 3).)

FF22 The Examiner notes that Morita compares the strength of a composite prepared containing poly-L-lactic acid embedded in microporous collagen sponge to glutaraldehyde cross-linked collagen sponge, wherein the poly-L-lactic acid reinforced sponge had a strength of 7.7 and the glutaraldehyde cross-linked collagen sponge had a strength of 1.3 (Ans. 10 (citing Morita, p. 3, Embodiment and Table 1)).

FF23 Vyakarnam is cited by the Examiner for teaching "foam structures that can be composed of copolymers of lactide . . . which can be used to regenerate tissue such as tubular structures such as vascular grafts." (Ans. 10.)

FF24 The Examiner further finds that Vyakarnam teaches that the foam may be reinforced with fibers made of calcium phosphate (*id.* at 11).

FF25 The Examiner concludes:

> It would have been obvious to use a sponge containing embedded fibers for reinforcement as the matrix of Vacanti et al for engineering tissues to obtain the function of the fibers in the sponge to maintain strength, shape and structural pores of the sponge as suggested by [Morita] and Vyakarnam et al since

> Vacanti et al disclose that the matrix can be spongelike (col 3, line 51), or can be a polyvinyl alcohol sponge (col 4, lines 25-26). Fibers in the sponge are integrated with the sponge, and blood vessels, arteries and heart valves produced by Vacanti et al are cardiovascular tissue. The function of the fibers to maintain strength, shape and structural pores of a sponge as taught by [Morita] and to reinforce a foam as taught by Vyakarnam et al would have been motivation to use a sponge containing embedded fibers for reinforcement. The fibers would have been expected to provide the function of strength to resist mechanical forces and maintain a desired shape provided by the struts of Vacanti et al, or in combination with the struts, to provide additional strength to resist mechanical forces.

(*Id.*)

ANALYSIS

Appellants argue that the Examiner has failed to establish a prima facie case of obviousness as there is no reason to combine the references as suggested by the Examiner (App. Br. 7). Appellants contend that neither Vacanti nor Vyakarnam teach or suggest the limitation of "the reinforcement being integrated with the sponge and located inside or on the exterior surface of the matrix," and Morita has nothing to do with *ex vivo* tissue engineering." (*Id.* at 8.)

As to the struts of Vacanti, Appellants assert that while Vacanti does not specifically disclose the structural relationship between the struts and cell-matrix structure, that "it seems clear that the struts are separate from the cell-matrix structure." (*Id.*) According Appellants, "modifying the Vacanti disclosure to place the struts inside inside or on the exterior surface of the matrix would render them incapable of carrying out the tissue pushing function disclosed, [thus] one of skill in the art would have no reason to

modify the Vacanti disclosure in this way." (*Id.* at 9.) Appellants assert further that because Vacanti teaches the use of unreiforced matrix, the ordinary artisan would have no reason to go to a reinforced matrix (*id.* at 10).

As to Vyakarnum, Appellants argue that the reference does not disclose the relationship between the foam matrix and the calcium phosphate reinforcing fibers, and the Examiner cannot use Appellants' disclosure to fill in the gaps (*id.* at 11). In addition, Vyakarnum uses the calcium phosphate fibers are restricted to the section of cartilage attached to bone, but does not disclose their use in vascular repair (*id.* at 12). Thus, Appellants assert, the ordinary artisan would conclude that "Vyakarnam's reinforcements would add undesirable stiffness, which would probably render the cardiovascular tissue graft unsuitable for its intended purpose," and that "would lead one of skill in the art away from the cited combination." (*Id.*)

Morito, Appellants assert, "does not disclose seeding and growing cells on the filler material prior to implantation, and does not disclose "that the filler material is used for regenerating blood vessels or similar cardiovascular tissue structures." (*Id.* at 13.) Appellants argue that Morita teaches that reinforcement is required until regeneration of the tissue, thus, "[b]y implication, regenerated tissue would not require the bioabsorbable reinforcement disclosed in Morita." (*Id.*)

Appellants argue that they "have discovered, quite unexpectedly in view of the cited prior art, that when an unreinforced material is employed, the resulting graft can fail catastrophically," and that the solution they came up with "is admittedly quite simple: reinforce the material with separate biodegradable reinforcement prior to seeding cells on it." (*Id.* at 3-4.) Appellants argue that the "Examiner erroneously focuses on the simplicity

of the solution rather than the nonobviousness of the problem." (*Id.* at 4.) According to Appellants, both Vacanti and Vyakartnam "disclose an unreinforced biodegradable fiber-based material for use in the production of cardiovascular graft tissue," and Appellants "were apparently the first to discover that this was wrong and that reinforcement of the starting material was required to avoid failure of the graft." (*Id.* at 5.) Appellants argue that "if bioabsorbable reinforcements were in fact needed in cardiovascular grafts, the prior art would have taught or suggested that such bioabsorbable reinforcements should be used. The fact it did not disclose or suggest the use of such bioabsorbable reinforcements is evidence that the use of such bioabsorbable reinforcements is not obvious." (*Id.* at 15.)

All of Appellants' arguments have been carefully considered, but are not convincing. Vacanti teaches the method of claim 7, including the use of a sponge as a matrix. The only thing that Vacanti does not specifically teach is the use of a matrix that has a reinforcement made of a bioabsorbable material, "the reinforcement being integrated with the sponge and located inside or on the exterior surface of the matrix." Morita, however, teaches the limitation of a matrix comprising a sponge . . . made of a bioabsorbable material, as well as a reinforcement made of bioabsorbable material, such that "the reinforcement being integrated with the sponge and located inside or on the exterior surface of the matrix."

Vacanti also teaches the use of struts, which are made of a bioabsorbable material that has sufficient strength to resist the necessary mechanical forces, may be used to create a more defined shape for the matrix (FF17). Vacanti also teaches that it was known that the erosion of the matrix is related to the molecular weight of the polymer used (FF16). Thus, Vacanti provides evidence that the ordinary artisan was aware that matrices

used in cardiovascular repair had to have enough mechanical strength for the application for which they were being used, and that different matrices have different properties.

Morita teaches that its reinforced matrix has increased strength when compared to a non-reinforced matrix (FF22). Morita specifically teaches the matrix for the broad application of the treatment of "wounds or defects," and while the matrix is not seeded before implantation, Morita teaches that the use of a biodegradable poly-L-lactic acid with the collagen sponge makes it possible to maintain structural pores of the sponge over a long period of time, and to promote the propagation of fibroblasts in the interior of the composite material, and maintain the strength and shape over a long period of time required for treatment (FF21).

Thus, we agree with the Examiner that the ordinary artisan, when presented with the teaching of Vacanti of the use of a seeded sponge matrix for use *in vivo* for regenerating cardiovascular tissue, and Morito's teaching of a sponge matrix made of a bioabsorbable material and a reinforcement made of bioabsorbable material, the reinforcement being integrated with the sponge and located inside or on the exterior surface of the matrix that has increased strength, would have recognized that the sponge matrix of Morita would predictably function in the cardiovascular regeneration method of Vacanti. Vacanti supports that conclusion in the patent's recognition that matrices used in cardiovascular repair had to have enough mechanical strength for the application it is being used, and that different matrices have different properties.

As to Vyakarnum, we conclude that it is cumulative to Vacanti and Morito. Vyakarnum does demonstrate, however, that it was known in the art

that one can use a reinforced matrix, although not specifically teaching its use for regenerating cardiovascular tissue.

As to Appellants arguments that they have discovered an unknown problem, that is, when an unreinforced material is employed for regenerating cardiovascular tissue, the resulting graft can fail catastrophically, the art need not be directed to the same problem to render the subject matter obvious. As discussed above, the ordinary artisan would have been motivated to use a reinforced matrix such as that taught by Morita in the cardiovascular regeneration method of Vacanti in view of Morita's discussion of its increased strength.

Finally, as to Appellant's argument that "if bioabsorbable reinforcements were in fact needed in cardiovascular grafts, the prior art would have taught or suggested that such bioabsorbable reinforcements should be used," and the "fact it did not disclose the use of such reinforcements is evidence that the use of such bioabsorbable reinforcements is not obvious," Appellants are essentially arguing that because the claimed method is novel, it is also not obvious. That clearly, however, is not the standard by which obviousness is determined.

Appellants also assert that the Examiner improperly discounted objective evidence of nonobviousness (App. Br. 14). Appellants assert that they have demonstrated that the graft that was not provided with a bioabsorbable reinforcement failed when it was grafted into the vena cava of a dog, whereas the graft having the reinforcement did not rupture after six months, and the blood vessel had regenerated (*id.* at 15).

It is well settled that in order to demonstrate unexpected results, the results must be shown to be unexpected compared with the closest prior art, and the results are commensurate in scope with the claims. Appellants

Specification provides only one example, in which a solution of L-lactide-caprolactone copolymer (50:50) in dioxane (5 %) was used as the matrix (FF7). Appellants have provided no analysis demonstrating how that example reads on the closest prior art. Moreover, Vacanti recognizes that the properties of the matrix differ depending on the material used, thus Appellants one example would not be sufficient to support any matrix and any bioabsorbable reinforcement material encompassed by claim 7.

CONCLUSION(S) OF LAW

We conclude that Appellants have not demonstrated that the Examiner erred in combining the references to arrive at the method of claim 7. In addition, as discussed above, the fact that Appellants discovered and solved a problem unknown in the art does not demonstrate the nonobviousness of the claims. Finally, we also conclude Appellants have not demonstrated unexpected results.

We thus affirm the rejection of claims 7-9, 11, and 15-19 under 35 U.S.C. § 103(a) as being obvious over the combination of Vacanti, Vyakarnam, and Morita.

ISSUE (Naughton)

The Examiner finds that the claims on appeal are rendered obvious by Naughton, either alone, or as combined with Vacanti, Vyakarnam, and/or Morita.

Appellants contend that Naughton does not teach or suggest the limitation of a reinforcement that is "integrated with the sponge and located inside or on the exterior surface of the matrix."

Thus, the issue on appeal is: Have Appellants demonstrated that the Examiner erred in concluding that Naughton renders obvious the limitation of claim 7 of a reinforcement that is "integrated with the sponge and located inside or on the exterior surface of the matrix"?

ADDITIONAL FINDINGS OF FACT

FF26 The Examiner rejects claims 7, 8, and 11 under 35 U.S.C. § 103(a) as being rendered obvious by Naughton (Ans. 13). As Appellants do not argue the claims separately, we focus our analysis on claim 7, and claims 8 and 11 stand or fall with that claim.

FF27 The Examiner finds that Naughton teaches "producing tissue *in vitro* by seeding cells on a three-dimensional framework having interstitial spaces, which can be shaped to assume the conformation of natural organs and their components." (*Id.* (citing Naughton, col. 4, ll. 63-64).)

FF28 The Examiner finds that Naughton teaches that the "three-dimensional framework can be formed of biodegradable matrices such as collagen sponge . . ., or polyglycoloc acid or polylactic acid and copolymers thereof." (Ans. 13 (citing Naughton, col. 9, ll. 59-62).)

FF29 The Examiner finds further that Naughton teaches the formation of tubular structures, such as blood vessels, arteries, and veins, and also teaches implantation of a valve (Ans. 13 (citing Naughton, col. 6, ll. 55-60; col. 19, l. 49; col. 22, l. 41; col. 24, ll. 33-37; col. 25, l. 24)).

FF30 The Examiner cites Naughton for teaching that stromal cells such as fibroblasts, in combination with other cells such as endothial cells or smooth muscle cells are grown on the framework in vitro, such that the cells and their secreted extracellular matrix proteins envelop the framework "to form a

three dimensional living stromal tissue." (Ans. 13-14 (citing Naughton, col. 4, ll. 23-44; col. 7, ll. 51-60, col. 11, ll. 9-25 and l. 64).)

FF31 The Examiner further cites Naughton for teaching that "[s]ince the inner walls of arteries are rich in elastin, an arterial stroma should contain a high concentration of smooth muscle cells which elaborate elastin," because the "elastin provides strength and elasticity required of blood vessels *in vivo*." (Ans. 14 (citing Naughton, col. 4, ll. 2-9 and col. 13, ll. 28-31).)

FF32 The Examiner concludes:

> When producing tubular tissue structures such are arteries, veins, blood vessels that are cardiovascular tissue as disclosed by Naughton et al, it would have been obvious to use collagen sponge as the framework in which cells are cultured to produce the tissue as suggested by Naughton et a1 (col 9, line 60). The extracellular matrix containing elastin produced during culturing stromal cells will result in the extracellular matrix being integrated with the sponge and functioning for reinforcement of the sponge prior to seeding the sponge with tissue specific cells. Naughton et a1 disclose that elastin is a necessary component of blood vessels and provides strength (col 4, line 5) to the vessels, and is normal component of arteries (col 13, lines 28-31).

(Ans. 15.)

FF33 The Examiner further rejects claims 9, 15, and 19 under 35 U.S.C. § 103(a) as being obvious over the combination of Naughton and Vacanti (*id.* at 16).

FF34 The Examiner also rejects claims 16-18 under 35 U.S.C. § 103(a) as being obvious over the combination of Naughton, Vacanti, Vyakarnam, and Morita (*id.* at 17).

ANALYSIS

Appellants argue that Naughton does not teach or suggest the limitation of a reinforcement that is "integrated with the sponge and located inside or on the exterior surface of the matrix." (App. Br. 16.)

Specifically, Appellants argue that one skilled in the art, reading the instant Specification, would interpret a bioabsorbable reinforcement as being an artificial fiber, nonwoven fabric, or film that is present before the cells are seeded, and not as matrix produced by a cell type seeded onto the sponge (*id.* at 16-17). Appellants argue further that the type of cells seeded onto the matrix of Naughton-fibroblasts-were used in the comparative example of the instant Specification, thus fibroblasts could not be seen as the reinforcement as the graft failed (*id.* at 17). According to Appellants, "Naughton simply suggests that tubular biological replacement tissue grown on an unreinforced matrix may successfully be used as cardiovascular replacement tissues *in vivo*." (*Id.*)

Again, Appellants arguments have been considered but are not found to be convincing. First, while we agree that claim terms are to be interpreted in light of the Specification, the Specification provides examples such as artificial fibers and nonwoven fabrics, it states that there is no limitation on the bio-absorbable materials to be used for the sponge and the reinforcement [FF6]. Thus, the bioabsorbable reinforcement of claim 7 encompasses the elastin produced by the cells seeded on the matrix of Naughton. Moreover, while the matrix of Naughton is seeded with fibroblasts, it is also seeded with a high concentration of smooth muscle cells which elaborate elastin, specifically because the elastin provides strength and elasticity required of blood vessels *in vivo*.

We therefore agree with the Examiner that the extracellular matrix produced by the seeded cells containing elastin reads on a reinforcement made of a bioabsorbable material that is located inside or on the exterior surface of the matrix.

As to the rejection of claims 9, 15, and 19 under 35 U.S.C. § 103(a) as being obvious over the combination of Naughton and Vacanti, as well as the rejection of claims 16-18 under 35 U.S.C. § 103(a) as being obvious over the combination of Naughton, Vacanti, Vyakarnam, and Morita, Appellants argue that the additionally cited references do not remedy the deficiencies of Naughton (App. Br. 17-18). That argument is not convincing for the reasons set forth *supra.*

CONCLUSIONS OF LAW

We conclude that Appellants have not demonstrated that the Examiner erred in concluding that Naughton renders obvious the limitation of claim 7 of a reinforcement that is "integrated with the sponge and located inside or on the exterior surface of the matrix."

We thus affirm the rejection of:

Claims 7, 8, and 11 stand rejected under 35 U.S.C. § 103(a) as being rendered obvious by Naughton;

Claims 9, 15, and 19 stand rejected under 35 U.S.C. § 103(a) as being obvious over the combination of Naughton and Vacanti; and

Claims 16-18 stand rejected under 35 U.S.C. § 103(a) as being obvious over the combination of Naughton, Vacanti, Vyakarnam, and Morita.

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

Ssc:

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